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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/773,409      | 02/09/2004  | Katsuhiko Hiejima    | NPR-152             | 6612             |

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| EXAMINER |
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KOHARSKI, CHRISTOPHER

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| ART UNIT | PAPER NUMBER |
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3763

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 04/10/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/773,409

Applicant(s)

HIEJIMA, KATSUHIRO

Examiner

Christopher D. Koharski

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 11-19, 21, 24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 20, 24 and 26 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

Examiner acknowledges the reply filed 2/1/2007, in which claim 1 was amended and claim 26 was added. Applicant's arguments regarding the abstract objection are persuasive and the objection is withdrawn. Currently claims 1-26 are pending for examination with claims 11-19, 21, 24 and 25 withdrawn due to a previous election restriction.

### ***Claim Objections***

Claim 8 is objected to because of the following informalities: Regarding claim 8, the claim contains a minor misspelling of the word "opend". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5-6, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Schneider et al. (5,322,518). Schneider et al. discloses a valve device for a catheter.

Regarding claims 1, 3, 5-6, and 26, Schneider et al. discloses a tube (13) arranged in a longitudinal direction, a female connector (77) having a hollow form opened at its front and rear ends with an opening taper portion (near 16) formed in the longitudinal position with an elastically deformable (23) hemostasis valve that is

Art Unit: 3763

longitudinally slidable in the opening, the hemostasis valve being made of a single member and having a body portion (23) with an opening (43) being elastically deformed in a radially inward position and being urged in a rearward direction by the elastic deformation of an element body portion (41) and an open/closable portion (24,26) being formed in a tapered shaped to open outwardly upon the deformation of the body portion (Figure 1 and 4) in a radially inward direction.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9, 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakajima (US2002/01286044). Nakajima discloses an indwelling catheter assembly.

Regarding claims 1-9, 20 and 22, Nakajima discloses an indwelling catheter comprising a tube (2) a female connector (1) having a hollow form (4b) and an opening

Art Unit: 3763

taper portion with tapers located in the body with a longitudinally slidably elastically deformable body located within the catheter body with an openable/closable portion (Figures 1-3, 5-6 and 9-12) that deforms radially outward with a duckbill type configuration. Additionally, Nakajima discloses a connecting taper portion wherein the male connector (6a) is inserted into the female connector causing the hemostasis valve to move forwardly wherein the inner needle (5a) is removable (Figures 1-3, 5-6 and 9-12).

Nakajima discloses the claimed invention except for a one-piece hemostasis valve. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the valve member (such as depicted in Figure 9, 4b and 3c connected by 8) of a single unitary piece, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

#### ***Claim Rejections - 35 USC § 103***

Claim 24 is rejected under 35 U.S.C 103(a) as being unpatentable over Nakajima in view of Vaillancourt (6,699,221). Nakajima meets the claim limitations as described above except the express use of the male connector being a syringe.

However, Vaillancourt teaches a bloodless catheter.

Regarding claim 24, Vaillancourt teaches a syringe used with an inline vein puncture assembly (Figures 1-4, see summary of invention).

At the time of the invention, it would have been obvious to use a syringe with the system of Nakajima because it is well known in the art and Vaillancourt teaches that is that syringes are used with inline vein puncture assemblies. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Vaillancourt.

***Claim Rejections - 35 USC § 103***

Claim 10 is rejected under 35 U.S.C 103(a) as being unpatentable over Nakajima. Nakajima meets the claim limitations as described above except for the elastic member being made of a rubber material.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the seal of rubber, since there are many well known elastic materials in the art used construct seal and valve assemblies, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

***Response to Arguments***

Applicant's arguments with respect to claims 1-10, 20, 24 and 26 drawn to the single piece element have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 2/01/2007 have been fully considered but they are not persuasive. In response to applicant's argument that the references fail to show

certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., negative limitation of "not by pressing open the openable/closeable position) are not recited in the rejected claim 1, only the single piece valve. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### ***Suggested Allowable Subject Matter***

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner suggest the addition of a claim limitation to the independent claims drawn to element 16 (the distal protrusion) depicted in Applicant's figure 5 to overcome the prior art of record.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

Art Unit: 3763

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

9/2/07



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